REMARKS

Claims 1-20 and 23-38 are pending in the application. Claims 16-20 and 23-24 stand rejected under § 112, ¶ 2. Claims 1-6, 8-10, 13-16, 18-19, 23, 25, 27-30 and 33-37 are rejected under § 102(b). Claims 1-3, 8-10, 13-20, 23-26, 28-30 and 33-38 are rejected under § 103(a).

§ 112, ¶ 2 REJECTIONS

Claims 16-20 and 23-24 stand rejected as indefinite because the Examiner states that method step (g) in claim 16 is unclear.

Method step (g) in claim 16 has been amended to recite "separating said attachment portion from a remainder of said enclosure such that said remainder is removable after said conduit is secured to said attachment portion. Step (g) plainly calls for separating the attachment portion from the remainder of the enclosure so the remainder can be removed (from the patient's body) after the procedure is completed, i.e., after the end of the conduit is secured to the attachment portion.

Referring to Figures 1 and Figures 3a through 3d, for example, the enclosure 27 includes an attachment portion 18 (which can be a sewing cuff) wherein the sewing cuff is attached to the heart. As explained at page 6 of the specification, in reference to Figure 1, "the apparatus 15 can include a heart attachment member, such as a sewing cuff 18 . . . ." The next sentence explains that the "apparatus 15 may be attached to a heart, as shown in Figure 2, using various surgical approaches."

At page 9, beginning at line 12, the specification explains "that the conduit 24 secured to the sewing cuff 18 -- not to the heart itself." Pages 9 and 10 go on to describe the procedure after

the sewing cuff is attached to the heart, in regard to coring a plug of tissue from the heart, inserting the end of the cannula/conduit through the opening, and securing the enclosure 27 to the conduit. The description on following pages detail various ways of sealing the enclosure around the conduit.

Finally, in the last sentence on page 15, the last step in the procedure is described wherein "the enclosure 27 can be dissected away from the inflow conduit and the sewing cuff 18."

The latter sentence provides explicit support for the limitation in part (g) of claim 16. It is clear from the description of the invention, that the "enclosure" is utilized only during the procedure to attach the conduit to the heart via the sewing cuff. Once this procedure has been completed, the sewing cuff and the conduit remain within the patient, and the other parts of the apparatus are removed from within the patient.

To do this, the extraneous portion of the enclosure (i.e., "the remainder" thereof) is dissected away from the conduit and the sewing cuff, and removed from within the patient along with the instruments that were contained in the enclosure.

Therefore, for all of these reasons, it is respectfully submitted that the limitation in part (g) of amended claim 16 is clear, unambiguous, fully supported by the specification, and thus in compliance with § 112, ¶ 2.

§ 102(b) REJECTIONS

Claims 1-6, 8-10, 13-16, 18-19, 23, 25, 27-30, and 33-37 stand finally rejected as anticipated by Sherman et al. '159 ("Sherman").

In addition to other features of the apparatus disclosed in Sherman, the Examiner characterizes Sherman as disclosing a "attachment portion or sewing cuff 26 separable from enclosure 12."

Applicant, and the inventors, have closely and carefully reviewed Sherman, and the "attachment portion or sewing cuff 26" referred to by the Examiner is, in fact, not "separable" from the apparatus.

Sherman describes that portion of the apparatus as follows:

> Each disk 24 is held in place by means of clip or pin 27 through hubs 26a. Rack 26 sits on ledges or lips 32 inwardly extending from respective protrusions or peak sections 20.
>
> * * *
>
> Rack 26 is positioned such that each disc rests upon a ledge 32. More particularly, the circumferential surface of each disk 24 is tangentially aligned with the annular needle passage such that, when an annular surgical needle 36 is operatively positioned within the annular passage, disks 24 frictionally engage needle 36.

Refer to col. 9, line 57-col. 10, line 11, referring to Figures 5 and 6.

Consequently, the rack 26 is not a separable part of the apparatus. Instead, it is held within the end of the apparatus and serves to support each disk 24 in a manner such that the circumferential surface of each disk 24 is tangentially aligned with the annular needle passage. As can be seen in Figures 5 and 6, and as just described above, the rack 26 is supported by "ledges or lips 32."

More importantly, as explained above in connection with the § 112, ¶ 2 rejection, the attachment portion in applicant's invention is that which is physically connected to the tissue and is cut away from the rest of the enclosure and remains connected to the tissue inside the patient,

whereas the remainder of the enclosure (and the apparatus that were contained in the enclosure) are removed from the patient's body.

In contrast, the apparatus for applying purse string sutures shown in Sherman has no portions which are detachable and which remain attached to the heart when the apparatus is removed. The suturing apparatus in Sherman is designed to apply sutures to the tissue and then be entirely removed from the patient's body. Unlike the claimed invention, no portion of the apparatus remains behind attached to the tissue.

Therefore, at least the attachment portion which is separable from the remainder of the enclosure is not shown or taught in Sherman. In order for a claim to be properly rejected under § 102(b), each and every element of the subject claim must be disclosed or inherent in the prior art reference. Accordingly, claims 1-6, 8-10, 13-16, 18-19 23, 25, 27-30 and 33-37 are patentable over Sherman.

§ 103(a) REJECTIONS

Claims 1-3, 8-10, 13-20, 23-26, 28-30, and 33-38 stand finally rejected as unpatentable over Sherman in view of Leahy et al. '409 ("Leahy").

The Examiner states that "Sherman et al. do not disclose an enclosure evacuated or filled with fluid." The Examiner then states that "Leahy et al. teach a flexible fluid-tight envelope or enclosure filled with insufflation fluid with an access port to provide a sterile environment for insertion of surgical instrumentation wherein the enclosure has an attachment portion or 'peel-strip backing' that is separable from the enclosure."

As discussed above, Sherman does not disclose an enclosure having an attachment portion wherein the attachment portion is separable from a remainder of the enclosure. Whether or not the enclosure is evacuated or filled with fluid is not considered important to the patentability of the independent claims, which are patentable over Sherman for the reasons explained above.

Moreover, Leahy also does not disclose an enclosure having an attachment portion and wherein the attachment portion is separable from the remainder of the enclosure.

The Examiner states that Leahy discloses a "attachment portion or peel-strip backing" that is separable from the enclosure." The "peel-strip backing" is separable from the "attachment portion," but the attachment portion is not separable from the enclosure. The peel-strip backing simply exposes an adhesive which is used to stick the "attachment portion" to the tissue. However, the "attachment portion" is subsequently removed, along with the rest of the enclosure, when the procedure is completed. Consequently, the "attachment portion" in Leahy is not separable from the enclosure as recited in the independent claims.

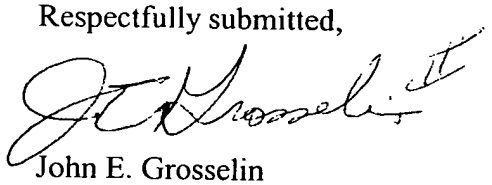
Therefore, claims 1-3, 8-10, 13-20, 23-26, 28-30, and 33-38 are patentable over Sherman and Leahy either individually, or any combination thereof.

CONCLUSIONS

Each of the independent claims particularly requires that an attachment portion which is separable from a remainder of the enclosure. Neither Sherman nor Leahy disclose or teach at least this element of the independent claims. Accordingly, claims 1-20 and 23-38 are believed to be patentable over Sherman and Leahy either alone or any combination thereof.

Therefore, reconsideration and allowance of claims 1-20 and 23-38 are respectfully requested.

Respectfully submitted,



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